European Commission DG SANTE
Unit D3 - Medical devices
Head of Unit

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via e-Mail ***uropa.eu***

Urgent need for action: Legal short-term measures to facilitate MDR/IVDR implementation in Q1 2025

Dear

Recital (1) of Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) states that the objective is "to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation". Furthermore, according to recital (2), the MDR and IVDR aim to ensure the smooth functioning of the internal market for medical devices, with a high level of health protection for patients and users, taking into account the small- and medium-sized enterprises active in the sector.

However, after more than six years of implementing these regulations, the availability of both long-standing and new modern medical devices in Europe has declined, negatively impacting patient care. The unpredictability, complexity and lack of harmonization, as well as the administrative burden of the regulations have led to high and unproportionate costs, product discontinuations and migration of innovation.

While the undersigned associations welcome a targeted evaluation in 2025 to further explore root causes and simplification, urgent legal measures are required now, to restore trust in the system and among all stakeholders, to protect patient care with both proven and modern medical devices, and to maintain the EU as a competitive center of innovation.

In line with the European Parliament's resolution of 23 October 2024 on the urgent need to revise the Medical Device Regulations (2024/2849(RSP)), we support a prioritized approach, beginning with short-term solutions that can be implemented through implementing acts. These measures also support EU Commission President von der Leyen's agenda to reduce bureaucracy.

Specifically, we propose the following deliverables for Q1 2025:

1. **Implementing Act regarding Annex VII**

Article 36 (3) MDR/ article 32 (3) IVDR allows the Commission to establish implementing acts in regard to the application of Annex VII. *„In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt an implementing act, to the extent necessary to resolve issues of divergent interpretation and of practical application."* Topics of major importance that could be addressed here are related but not limited to e.g. establishing a common understanding of the steps and timelines for conformity assessment in order to enhance predictability, efficient change notification and management, structured dialog, content of a written agreement ensuring a level playing field, templates for certificates, Notified Body contract, and technical documentation structure and format. More details regarding possible measures within this legal act are highlighted in yellow in the attached list.

2. **Implementing Act regarding clinical evidence**

To *"ensure the uniform application of Annex XIV, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application"* (see article 61 (13) MDR/ article 56 (7) IVDR). Also, in order to achieve a *"uniform application of the requirements regarding the clinical evidence or data needed to demonstrate compliance with the general safety and performance requirements set out in Annex I"* the Commission may establish implementing acts (see article 81 (g) MDR/ article 77 (g) IVDR). Other specific provisions also allow for implementing and delegated acts (e.g. article 32 (3), article 52 (5) MDR/ article 29 (3), article 48 (13) IVDR). Questions in regard to the summary of safety and clinical performance (SSCP), the concept of well-established technologies and to making use of the possibility outlined in article 61 (10) MDR can thus be addressed. Possible measures are marked in green.

3. **Adapt certification to follow a life cycle approach**

Today, recertification for medical technologies is required every 5 years, which represents a high bureaucratic effort and re-investment burden without resulting in additional safety benefits. This is because the Notified Bodies are already required to continually assess devices and quality systems after their certification on an annual and ongoing basis. Therefore, there is an immediate need for aligning certification with the life-cycle approach introduced by the regulations in order to avoid unnecessary bureaucracy, costs and potential bottlenecks. Proposals to do so are outlined in blue.

4. **Implementing Act in regard to the digitalization of processes and documents/eIFU**

Results of multiple surveys show that the current framework for the very limited use of electronic instructions for use is outdated. A broad application of electronic instructions for use will help reduce

bureaucracy and protect the environment. Improvements in regard to e-labelling and digitization of processes are also needed. Proposed solutions are highlighted in purple.

5. **Implementing act regarding Classification rules as well as pathways for orphan devices and breakthrough innovations**

Article 51 MDR/ article 47 IVDR allows for the Commission to decide by means of implementing acts on issues that refer to the application of Annex VIII, that is classification and/or reclassification of a given device or category or group of devices. There are a number of proposals in this regard that are outlined in red.

In summary, the compilation of these solutions would immediately reduce administrative and financial burden for manufacturers and Notified Bodies, without compromising the safety or performance of medical devices or patient well-being. Swift implementation would also enhance the EU's innovative strength and global competitiveness.

Following this, a supplementary amendment to the regulations should be enacted within 2025. Additional proposals that should be considered for this amendment as well as ongoing short term specific measures to improve the implementation of the regulations are also provided (without colour) in the following table.

For the benefit of patients, the national healthcare economy, industry, and the EU as a vital business and innovation hub, the original objectives of the MDR/IVDR can only be achieved by addressing all steps mentioned above.

We would be pleased to provide a more detailed explanation of the points outlined. Please don´t hesitate to contact us in case of questions.

Best regards

[redacted]

on behalf of the above listed associations
Attorney at law / In-house Council
Director Regulatory and EU-Affairs SPECTARIS

Joint Opinion of D-A-CH region industry associations: Urgent need for legal measures to facilitate MDR/IVDR implementation

Annex I | D-A-CH region industry associations proposals for urgent measures to decrease bureaucracy and facilitate MDR/IVDR implementation

15.11.2024

Content

1. Better planning of the certification processes to ensure predictability

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
1.	Establishment of binding deadlines for the conformity assessment procedures	Diverging NB practices Lack of clear and binding timelines in the MDR / Annexes	Currently, there are significant delays in procedures, making it nearly impossible for manufacturers to plan the review of technical documentation and the overall completion of the conformity assessment and certification. Additionally, timelines for conformity assessment differ greatly between Notified Bodies.	To define a binding overall timeframe for the conformity assessment and certification procedure is the only way to give manufacturers the essential planning certainty they need in order to market products. This planning certainty is existential and urgently needed to secure the EU and Member State markets as a business location. First, it is essential that there is a common understanding of the necessary steps in the process and when and how these can move forward. Where possible, steps in the process should be able to run in parallel. Fixed timelines should be predetermined and implemented at least for some	Establish a common understanding of necessary steps in the conformity assessment process, introduce predetermined timelines for at least some of the steps, and predefine a binding overall timeframe for the whole process. Integrate a clock stop mechanism.	Implementing act according to Article 36 (3) MDR/32(3) IVDR to adapt Annex VII by • establishing a common understanding of necessary steps in the conformity assessment process • introducing predetermined timelines for at least some of the steps • predefining a binding overall timeframe for the whole process. integrating a clock stop mechanism.	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
				steps (e.g. application received, processed and assessed for completeness xx days; conclusion of a contract xx days, final issuance of the certificate after successful conformity assessment procedure xx days) Further timelines should be specified and predetermined in regards to specific conformity assessment activities. Any deviations (e.g. for necessary processing of non-conformities) from the schedule can be made after consultation with and approval by the manufacturer. The evaluation of a medical device is officially stopped with a clock stop for the amount of time the applicant needs to respond to questions. The clock resumes when the applicant has sent its responses.	Amendment of Annex VII Section 4.5.1 MDR: "The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields. The notified body shall confirm completeness or reject an application for conformity assessment within 10 days as of the date of application. If the notified body decides that the application is complete this is deemed to constitute an offer of a contract that may be accepted by the manufacturer. The notified body shall ensure that the procedure for conformity assessment is completed within a maximum of 180 days after the submission of a valid application, excluding consultation with competent authorities as part of the conformity assessment procedure. A clock stop is foreseen."		Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
2.	Technical documentation structure | Master Document	Divergent notified body practice	Notified body reviewers do not accept modular TD but rather expect parts of TD that they review to contain all information for the relevant part of the review. This includes also the fact that every document has to include every information, no references are allowed. A standardized TD should also be compatible with international documentation standards to reduce the overall bureaucratic burden.	As a result of diverging interpretations of the structure of TD between notified bodies, manufacturers cannot use a single 'organised, readily searchable and unambiguous' TD. The Team-NB BPG on technical documentation does not provide for harmonisation of interpretation on this point.	Option 1: Article 9 (1) MDR/IVDR: Commission to adopt CS regarding Annexes II and III by means of implementing act.	CS adopted by the Commission would provide a standard template for the TD structure that cannot be subject to divergent practice by notified bodies anymore. Use one master document and allow references in documents of the technical documentation to „other" documents or „parts" of documents in the same technical documentation; reduce any redundant texts/figures. If this takes more time for the notified bodies in reviews, the review fees should be fixed (!). And if partial documents (PEP/PER)	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						are reviewed by other experts, then these experts need to get access to any referenced documents to have complete information. An implementing act adopted by the Commission could resolve multiple issues regarding the application of Annex VII, including aspects related to conformity assessment activities. Thus, a standard template for the TD structure that cannot be subject to divergent practice by notified bodies anymore, could be implemented and combined with further measures, for example in regard to timelines.	Short term
3.	Technical documentation format	MDR/IVDR requirement Divergent notified body practice	The MDR should contain a uniform electronic structure for the technical documentation. In practice each notified body can determine how precisely the manufacturer should organise the	Making the TD specific to a specific notified body's requirements makes switching between notified bodies and market surveillance much more difficult. A standard format	Option 1: Article 9 (1) MDR/IVDR: Commission to adopt CS regarding Annexes II and III by means of implementing act.	CS adopted by the Commission would provide a standard electronic format for	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			technical documentation. There are examples of notified bodies that require manufacturers to re-format and in some cases disassemble their technical documentation only to make it fit to the specific notified body's system.	would make this much easier and less costly. Also, standard technical documentation improves market surveillance, as it will lead to increased transparency to technical documentation.	Option 2: Article 36 (3)/32 (3) IVDR In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt implementing acts, to the extent necessary to resolve issues of divergent interpretation and of practical application.	the TD much like the eCTD for medicines.[1] An implementing act adopted by the Commission could resolve multiple issues in regard to the application of Annex VII, including aspects related to conformity assessment activities. Thus, a standard format for the TD that cannot be subject to divergent practice by notified bodies anymore, could be implemented and combined with further measures, for example in regard to timelines.	Short term
4.	Structured dialogue | Clinical Evidence	Notified Body practice / Team NB code of conduct Competent Authority practice	Article 61 (1) MDR requires that conformity of the device shall be based on clinical data providing sufficient clinical evidence". In practice it is often not possible for the manufacturer to determine what will be sufficient clinical evidence for the device. This is exacerbated by the fact that also the latest version of the Team NB	Currently, it is still not possible to discuss a clinical development strategy in a structured dialogue and rolling review. Such a discussion is, however, necessary and should allow the notified body to, when the level of evidence is not deemed acceptable,	• Commission to adopt implementing act based on article 36 (3) to add to section 4.5.1 of Annex VII a specific obligation for the notified body to have a procedure for structured dialogue that includes - among other things - discussion of and feedback		Short term

[1] See White Paper BVMed and VDGH, section 4.5.3

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			Code of Conduct does not allow for the notified body to "Review clinical development strategy". Pre-submission meetings for precisely this purpose are a normal procedural phenomenon for medicines marketing authorisation applications, intended to discuss details regarding the procedure with the persons responsible at the government body. However, the MDCG does not provide any transparent detail on what a structured dialogue would look like. Moreover, MDCG refers the further implementation its subgroup the NBO (one of the two MDCG subgroups that **does not** admit stakeholders). This is counterproductive as input from what is needed in practice is essential in this regard.	indicate what is not acceptable and why.	on sufficiency of clinical evidence. • Member states to instruct notified bodies that structured dialogue may include discussion of clinical development strategy, including indication of what evidence is not deemed acceptable. This does not constitute prohibited consultancy and should be explained accordingly with reference to ISO 17021-1:2015, which addresses consultancy explicitly and provides a number of examples that do not constitute consultancy such as clarifying requirements (sections 3.3 and note to section 5.2.5[2]).		

[2] "The certification body and any part of the same legal entity and any entity under the organizational control of the certification body […] shall not offer or provide management system consultancy. […] NOTE This does not preclude the possibility of exchange of information (e.g. explanation of findings or clarification of requirements) between the certification body and its clients."

2. Proportionate assessment of the clinical evidence/performance

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
5.	SSCP | Exemption for Well Established Technology (WET)	MDR requirement Lack of optimisation	WET implants are subject to SSCP obligation (article 32 (1) MDR), while they are exempted from other document requirements under the MDR, such as implant card (article 18 (3) MDR) and assessment of the technical documentation (Art. 52(4) 2nd section). This forces the manufacturer to produce and validate an SSCP for a device that does not (or no longer) change in any material sense, because the technology is well-established. SSCP obligations are not suitable for WET, because periodic updates to the SSCP will not reveal new	The very fact that the technology is well-established means that yearly updates of the SSCP in accordance with article 61 (11) MDR are redundant exercises. The initial SSCP for initial conformity assessment is sourced completely from the TD, so will not contain any new information compared to the IFU. HCPs and patients have no use for SSCP for WET precisely because it is well-established and will therefore not differ materially from the IFU. For this reason, WET implants are exempted from having an	[**option 1**] Implementing act based on article 32 (3) MDR	Implementing act to clarify that "implantable devices" for the application of article 32 exclude the following" "sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and any other implants exempted from the obligations in article 18"	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			developments relevant to health care professionals (HCPs) and patients.	implant card (article 18 (3) MDR).	[**option 2**] Amendment of article 32 (1) MDR to exclude the same WET devices as excluded under article 18 (3) MDR	Add in article 32 (1) MDR behind "other than custom-made or investigational devices" the following "sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and any other implants exempted from the obligations in article 18".	Mid term
					[**option 3**] Amend article 61 (11) to exempt WET from yearly SSCP publication	Change of article 61 (11) MDR to provide after "and, if indicated, the summary of safety and clinical performance referred to in Article 32" in article 61 (11) 2nd paragraph "expect for sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and any other implants exempted from the obligations in article 18."	

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
6.	Definition of Well-Established Technologies (WET) subject to exemptions under articles 52 (4) and (5) MDR	MDR requirement	The use of the general terms "sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors" for WET in article 54 (4) and (5) and other places in the MDR beg the question for a more precise and at the same time more flexible definition of WET to reflect the intention of the EU legislator.	Clearly, the EU legislator sought to create a category of devices within the same risk class of implants that would be subject to lighter conformity assessment because the technology is well-established. The concept of WET could be established better by adding more general types of devices to the group listed in article 52 (4) MDR, which the Commission is entitled to do by delegated act based on article 52 (5) MDR. This would allow updating the list on the basis of experience gained with the application of the MDR and it would reduce the administrative burden for manufacturers of the devices concerned considerably because these devices can be approved on a sampling basis rather than dossier examination (see article 52 (4) MDR.	Delegated act by the Commission pursuant to article 52 (5) to amend the article 52 (4) list with more general types of implantable devices.		Short term
7.	SSCP frequency (yearly update)	MDR requirement Lack of optimisation (considering the state of the art)	The PMS process should be capable of being automated and statistics driven to ensure that costs for compliance are kept at reasonable levels and processes are appropriate for the devices concerned. PMS and PMCF should not be about producing data	Yearly publication and validation of an SSCP is an extremely time consuming and costly process, which needs to be conducted also if there are no relevant changes to report. This can be implemented by means of a small amendment	[**option 1**] Implementing act under article 61 (13) MDR for setting out KRIs (Key Risk Indicators) that would trigger an SSCP update;		Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			periodically and putting this in reports to be evaluated by a third but rather about detecting signals relevant to PMS and PMCF and informing HCPs and patients on a targeted basis. Targeted information will perform better than periodic similar reports in which it is not clear what has changed.	to Article 61 (11) MDR or could be done by means of an implementing act based on article 61 (13) MDR, supported by MDCG guidance. In addition, the scope of devices for which an SSCP is considered relevant by the MDCG in MDCG 2019-9 is overly broad as there is no evidence that an SSCP actually benefits or even reaches patients. If there are issues with the devices concerned that patients must know about this can be better achieved through other channels than Eudamed. The notified body is needed for any interaction with Eudamed for SSCPs but this creates administrative costs and delays – the manufacturer should be able to upload documents himself that are validated in Eudamed by the notified body if needed.	[**option 2**] Adopt CS based on article 9 (1) to amend PMCF in Annex XIV to define KRIs for PMCF that would trigger need for SSCP update.		Short term
					[**option 3**] Amendment to article 61 (11) 2nd paragraph MDR	Article 61 (11) 2nd paragraph is amended as follows: "For class III devices and implantable devices, the PMCF evaluation report ~~and, if indicated, the summary of safety and clinical performance referred to in Article 32~~ shall be updated at least annually with such data. <u>The summary of safety and clinical performance referred to in Article 32 shall be updated with data if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete.</u>"	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
					Amend MDCG 2019-9 on SSCP to clarify that the patient part of SSCP is only needed in cases where this is relevant and not in all cases of class III and implantable devices for which patients receive an implant card and that the manufacturer can upload non-validated documents and translations of SSCP without the intervention of the notified body.		Short term
8.	SSP only for products used directly by laypersons ("selftests").	IVDR requirement	SSP is not seen by the patient. In addition, professional users have already access to the instructions for use, containing already a lot of information also being part of the SSP and they are often in contact with the manufacturer's experts. Consequently, professional users don't need any SSP as well.	SSPs are made for patients to get an insight into the performance of the test. professional tests are "not seen" by the patient, so the SSP is not needed. SSP is a high bureaucracy burden (check, upload, validation, translation). Additionally, there is a high overlap with the IFU.	Amendment to article 29 (1) IVDR as follows: 1. For class C and D **lay use device**s, except for devices for performance studies, the manufacturer shall draw up a summary of safety and performance.		Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
9.	CECP application requirement	MDR requirement	Pursuant to Article 54 (1) MDR and subject to limited derogations under Article 54 (2) MDR the CECP must always be followed. Yet, the expert panel (EP) rarely issues an opinion after an application by the Commission's data (12% of the cases in the period of July 2022-July 2023).[3] However, this percentage only concerned screened applications. When calculated over all applications made (353) in that period the percentage turns out to be 1%. This leads to a vast amount of unnecessary applications to the expert panels and unnecessary	Use of CECP must be adapted given the fact that 99 % of the applications are unnecessary as they do not lead to an expert panel opinion. Under the current requirements an application must always be made. If the MDR could specify criteria or provide for the option to define them, the number of unnecessary applications could be reduced radically. Even more important, the decision whether the device deserves an opinion of the EP	• **Option 1:** On the basis of Article 54 (5) MDR the European Commission may make proposals for amendments to the regulation. Amend Section 5.1 (a) Annex IX and 6 Annex X criteria or procedure for certain devices ("For class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product as referred to in Section 6.4. of Annex VIII (Rule 12)")		Mid term

[3] The Commission's most recent report states that this happens in 12% (SWD (2024) 76 final, p. 7 (Annual overview of devices subject to the clinical evaluation consultation procedure pursuant to Article 54(4) of Regulation (EU) 2017/745 on medical devices (July 2022- June 2023)

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			work by the notified bodies to prepare them and shows that the application criteria should be adapted. Even if NBs use exemptions per Art. 54(2) or if the EPs do not provide opinions based on provisions per Annex IX, 5.1 c., the NB needs to prepare and submit a wealth of documents to numerous authorities which remain predominantly unread. Moreover, the CECP process is utilized at a time the review process for the device is completed and therefore the CECP occurs on the "time-critical path" of the conformity assessment project.	should be decided early in the conformity assessment project off the time-critical path.	• **Option 2** Adopt CS for devices' clinical evaluation that excludes them from the CECP		Short term
10.	CECP procedure	MDR requirement Lack of optimisation (considering the state of the art)	CECP procedure is inefficient and designed to be completely linear with institutions waiting for each other to complete processes where processes could be completed in parallel.	The processes at EP and NB must run in parallel in order to save time, resources and effort without jeopardising the safety or quality of the product or concealing a product from the experts. This also includes a collection obligation of the screening panel, if necessary.	Amendment of Annex IX 5.1	Amendment of Annex IX 5.1 on the following points: • NB requests slot for panel review at EP secretariat upon receipt of conformity assessment application for device(s) concerned. Secretariat gives notified body date for delivery of CER to EP secretariat.	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						EP secretariat delivers CER to Commission if needed for Commission involvement in EP decision under (c) and (d). • Presentation of NB conclusions takes place within the 60 days period under 5.1 (c). • 60 days starts on delivery of CER to EP secretariat. • EP decides within 14 days about whether or not to give opinion. • Same as under (d) EP decides within 14 days about whether or not to give opinion. • [no change] • Remove sentence "Where the expert panel [...] as appropriate." The notified body shall set out in the CAR how it has taken the EP advice into	

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						account. This is not published publicly although the EP opinion may be after anonymisation pursuant to article 109 MDR. The Commission shall evaluate EP opinions and periodically and based on this evaluation update guidance for expert panels for consistent interpretation of the criteria in point (c)	
11.	Scope of article 61 (10)	Notified Body practice Competent Authority practice	Article 61 (10) MDR allows for the manufacturer to adequately demonstrate and justify conformity with the general safety and performance requirements (GSPR) based on the results of non-clinical testing methods alone.	It is important that this option, that is already outlined in the legal text, is applied and made functional. With the current advances in technology, medical device testing environment are expanding. Considering this,	• Article 61 (13) MDR allows the Commission to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application of Annex XIV MDR.	Implementing act according to Art. 61 (13) MDR regarding the use of non-clinical data to demonstrate conformity with the applicable GSPRs as well as examples of devices in scope.	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			In practice, however, this option is not applied and/or accepted by NB. For example[4]: Notified bodies require clinical data for devices that are not intended to be used on humans (e.g. devices for cleaning, disinfection and sterilisation). Article 61 (10) MDR is creating uncertainty on its interpretation and correct application, especially for medical devices falling into the low to moderate risk class (Class IIa) and in the moderate to high (class IIb) risk class, where the requirement to perform a clinical investigation for the demonstration of conformity with the GSPRs is not imposed by the legislation.	digital twinning, curative databases, computer modelling, use of physical or digital phantoms, generation of artificial (patients) data or use of retrospective patient data may provide controlled and scientifically valid concept to be utilized as non-clinical data within the device's clinical evaluation. The focus on the assessment within the clinical evaluation should be on scientific validity of the testing methodology, test case design and the output, whether the data can be extrapolated to the expected clinical use of the device and in the intended clinical use environment, and whether the non-clinical data solely is sufficient to cover all clinically relevant characteristics and claims made on the device by the manufacturer, and thus demonstrate the conformity of the device with the applicable GSPRs.	• In the meantime, Member States and Commission to raise awareness and instruct notified bodies to allow and make use of Article 61 (10) MDR.		Short term
					• MDCG guidance about type of devices in scope of article 61 (10) and regarding the use of non-clinical data to demonstrate conformity with the applicable GSPRs.		Short term

[4] For more examples see also: 20220525_COCIR_White_Paper_MDR_Article_61__10_.pdf

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
12.	Need of PMCF studies | required by notified bodies if MDR does not specifically call out the need	Notified Body practice Competent Authority practice	PMCF under the MDR and under the previous MDD/AIMDD differs. Under the MDR it is a life cycle PMS process, whereas under the MDD/AIMDD it referred to conditions that a notified body would impose to be fulfilled by the manufacturer as a condition for continued validity of the CE certificate.[5] Notified bodies occasionally require PMCF studies under the MDR as a condition for continued validity of the CE certificate like under the MDD/AIMDD.	Annex XIV Part B 6.2 (b) MDR provides that the PMCF plan shall include at least "the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies". PMCF studies are therefore not a requirement but specifics of the PMCF plan. Only where the PMCF plan itself states that PMCF study is indicated should there be a need to do PMCF studies. Otherwise, the NB could only find that the clinical data supporting that the device is not up to the state of the art (PMS goal in article 83 (3) (c) MDR[6]) and suggest to the manufacturer to collect additional state of the art data, leaving it to the manufacturer to determine the right instrument for this purpose.	No specific instrument required. Notifying authorities of Member States to clarify PMCF under MDR to notified body.		Short term
13.	Qualification of PMCF studies without additional invasive or burdensome procedures	MDR requirement	Article 74(1) MDR explicitly regulates only notifiable PMCF investigations, if the subjects are submitted to invasive or burdensome procedures in	This leads to **confusion, misunderstandings, and divergent practices** among Member states as some classify such PMCF investigations as	**Targeted change to the MDR legal text art 74:** Clarification of the legal classification of post-market clinical investigations of a	Proposal Art 74(3) MDR (new): "The provisions of Articles 62 to 81 shall not apply to PMCF	Mid term

[5] See MEDDEV 2.12/2 Rev. 2

[6] "to update the clinical evaluation;"

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
		Competent Authority practice Guidance or other interpretation of MDR legal text	addition to the normal conditions of use of the device. PMCF investigations without such additional invasive or burdensome procedures are not explicitly regulated in Article 74.	other clinical investigations per Art. 82 MDR. However, this is incorrect, since PMCF investigations are in general conducted for one of the purposes set out in Article 62(1) of the MDR, such as data collection as part of the ongoing conformity review. This explicitly excludes them from the scope of Article 82 (1) MDR.	device **within the scope of its intended purpose**, in which subjects are NOT submitted to additional invasive or burdensome procedures compared to the normal conditions of use of the device ("Non-notifiable PMCF investigations").	investigations in which subjects are not submitted to additional invasive or burdensome procedures compared to the normal conditions of use of the device."	
14.	Clarification on documentation needed for PMCF investigations per Article 74(1) MDR (with additional invasive or burdensome procedures, within the intended purpose)	MDR requirement Competent authority practise Guidance or other interpretation of MDR legal text	These investigations must be notified accordingly and the **complete documentation per Annex XV** MDR is required for the Ethics Committee assessment and for the CA notification. Annex XV does currently not differentiate between documentation requirements for clinical investigations subject to **authorisation** and clinical investigations subject to **notification**.	This is only justified for devices without CE marking, as the conformity assessment procedure has not yet been completed and the authorities must assess safety and performance. However, if a CE-marked device is to be investigated only with additional burdensome or invasive procedures there is no reason to (re)request this technical documentation and summarise it in an investigator's brochure, since the safety and performance have already been demonstrated in the conformity assessment (plus CIP and IFU).	**Targeted changes to the MDR legal text art 74 (and related articles accordingly):** Clarifications of the content of the documents to be submitted for post-market clinical investigations of a device **within the scope of its intended purpose**, in the context of which subjects are submitted to additional invasive or burdensome procedures compared to the normal conditions of use of the device ('Notifiable PMCF investigations').		Mid term
15.	Correction of timelines for submission of the	MDR requirement	In the case of an **early termination,** a lot of preparatory activities are not possible: In these	In the case of **an early termination**, it takes more time to compile the data and write	**Targeted change to the MDR legal text art 77(5):**	Proposal Art 77(5) subparagraph 1 MDR/Art 73(5) IVDR*:*	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
	final report for clinical investigations according to Art 77 (5) MDR/Art 73 (5) IVDR	Guidance or other interpretation of MDR legal text	cases, the clinical investigation is still ongoing and some non-monitored data are available at the study sites, queries are open, SAE status is not conclusively known, and in blinded study arms, the assignment is not yet known. In case of a **temporary halt**, priority must be given to whether and under what changed conditions this clinical investigation can be resumed, and a substantial amendment must usually also be submitted with appropriate measures to ensure the safety of the investigation subjects. Root cause analysis, determination of corrective actions and adaptation of documents, and submission pending approval of a significant change are the essential steps in this situation.	the final report than for a regular termination. The period of 3 months is not achievable in practice. In case of a **temporary halt**, a final report is not expedient and stands in the way of continuing the study, since the analysis and disclosure of the data obtained up to that point makes the continuation of the study subject to a considerable bias, especially in the case of well-designed clinical investigations (with randomization, blinding, ...).	It is proposed that the deadline for prematurely terminated clinical investigations should also be set at 12 months and that no final report should be required for temporarily halted clinical investigations, as these clinical investigations have not yet been terminated by definition.	"(5) Irrespective of the outcome of the clinical investigation, within one year of the end of the clinical investigation or ~~within three months~~ of the early termination ~~or temporary halt~~, the sponsor shall submit to the Member States in which a clinical investigation was conducted a clinical investigation report as referred to in Section 2.8 of Chapter I and Section 7 of Chapter III of Annex XV.(MDR)/ Section 2.3.3. of Part A of Annex XIII (IVDR)"	
16.	Correction of application for extension of the deadline of the final report according to Art 77 (5) subparagraph 3 MDR/ Art. 73 (5) IVDR	MDR/IVDR requirement Guidance or other interpretation of MDR legal text	The requirement stated in subparagraph 3 of Article 77 (5) MDR/ Art. 73 (5) IVDR is hardly feasible, because it requires that the scientific justification for exceeding the deadline of one year after completion should already be stated **in the clinical investigation plan**.	Experience of sponsors or their contract data processors shows that the scientific reasons why the final report cannot be completed on time only emerge during the evaluation and reporting phase.	**Targeted change to the MDR legal text art 77(5) subparagraph 3**/ Art. 73 (5) IVDR**:** A possibility should be provided to grant the sponsor an extension of the deadline upon request.	Proposal Art 77 (5) subparagraph 3 MDR/ Art. 73 (5) IVDR*:* "Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year of the end of the investigation, it shall be	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						submitted as soon as it is available. In such case, ~~the clinical investigation plan referred to in Section 3 of Chapter II of Annex XV~~ the sponsor submits an application for an extension of the deadline to the Member States no later than 3 months before the due date of the final report. This application shall specify when the results of the clinical investigation are going to be available, together with a justification."	
17.	Annex XIII.2.3.2 IVDR: Requirement of Clinical Performance Study Plan / Report.	IVDR requirement	Both documents have no real benefit. The existing Clinical Performance Protocol (that has already been established under IVDD) and the Clinical Performance part of the PER already contain most of the information. CPSP contains the same information as other documents (e.g. Intended Purpose / metrological traceability from PEP). Triggers extra work.		Update Annex XIII and delete the 2 documents.		Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
18.	Clarification of the timeline of Article 70(7) MDR	MDR requirement Very different application by Member States	The timeline mentioned in Article 70(7) MDR is interpreted very differently by the Member States. In some Member States the sponsor has to wait much more longer to be notified of the final authorisation. Also, it should be clearer that the extension of the period by the Member State is possible for a maximum of 20 days. In practice, some Member States interpret this possibility differently.		Targeted change to the MDR legal text Art. 70(7) MDR: A clarification of the timeline of Art. 70(7) MDR is needed.	Amendment to Art. 70(7) MDR: "(b) in the case of investigational devices, other than those referred to in point (a), as soon as the Member State concerned has notified the sponsor of its authorisation, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation. The Member State shall notify the sponsor of the <u>final</u> authorisation within 45 days of the validation date referred to in paragraph 5. <u>During the validation, the period of time is officially stopped while the applicant prepares responses to questions from the Member</u>	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						State («clock stop»). The Member State may extend this period by a maximum of further 20 days for the purpose of consulting with experts.”	

3. Recertification / reassessment of certificate validity

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
19.	Validity of certificates / Optimisation of the certification process / PMS controlled regulatory certification (process)	MDR/IVDR requirement	**Reassess provisions on the validity of certificates and optimize the certification process, taking into account the life cycle approach.** There is no objective justification for a five-year certification duration in the case of devices and the MDR and IVDR have significantly increased PMS (including PMCF-PMPF activities) to ensure continued compliance of the device throughout its life cycle, certificates should have unlimited duration (subject to PMS and PMCF/PMPF) or at least substantially extended and duplication of activities in re-assessment should be avoided. A certificate, once granted, should be subject to the many PMS controls under the MDR and IVDR only and should not be subject to periodic renewal. **PMS controlled market access**		It could be contemplated to interpret the duration of the certificate as an Annex XII element (see Annex VII 4.11), in which case the Commission could amend the MDR by delegated act pursuant to article 56 (6) MDR/article 51 (6) IVDR	"The certificates issued by the notified bodies in accordance with Annexes IX, X and XI for devices shall be valid for the lifetime of the device, subject to the manufacturer's post-market surveillance system supporting the quality, safety and performance over the lifetime of the device in accordance with Chapter VII, Section 1 and Part B of Annex XIV. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid."	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			Where a device performs as intended and the manufacturer demonstrates this on a continuous basis with PMS and PMCF/PMPF data, there is no reason to periodically revisit the certification decision, and the certificate can continue to be valid subject to appropriate surveillance by the notified body. Continued certificate validity should rather be risk and data based, based on PMS and PMCF/PMPF performance by the manufacturer as monitored by the notified body. If the manufacturer's PMS and PMCF/PMPF real-world data show that the device performs as intended after CE marking and to the state of art as is required under MDR or IVDR PMS and PMCF/PMPF requirements, there is no objective reason to repeat the certification, and the notified body can earmark a certificate as in good standing without need to be re-issued.		Amendment of article 56 (2) MDR/Article 52 (2) IVDR and corresponding provisions in the Annexes (e.g. Annex VII 4.11) by legislative change to MDR		Mid term
20.	Elimination of an annual certificate usage /maintenance fee.	MDCG guidance 2023-2 NB practice	MDCG 2023-2 includes a list of standard fees for "**conformity assessment activities**". It is not justifiable why notified bodies are able to charge an (internal) annual "maintenance fee" that is not part of conformity assessment activities	MDCG 2023-2 in regard an annual maintenance fee goes beyond MDR and needs to be eliminated.	Change of existing MDCG guidance	Adapt MDCG 2023-2. Eliminate "Annual certificate maintenance fee" as it is not justified.	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			rendered to a manufacturer. It is completely unclear and not explained (contrary to what it says in the guidance) what particular "activity" would justify another annual fee for "maintenance". As part of the surveillance obligations, notified bodies conduct audits on at least an annual basis. These activities are already subject to fees charged, as well as any other service in relation to the conformity assessment activities (e.g. changes, issuance of certificate etc.) It is not plausible at all that a company should pay continuously for the *use* of a certificate when the one-off service– i.e. the issuing of the certificate – has long since taken place and has already been paid for.				
21.	Harmonized content of a certificate across the EU	Diverging NB practices	Currently, no standard templates for certificates exist. The current different interpretations of the notified bodies are causing confusion among authorities outside the EU.	It would be beneficial to specify the content and design of the certificates in order to harmonize this across the EU and make communication with authorities outside EU easier.	Standard template for certificates		Short term

4. Adapt procedures for and content of some MDCG guidance documents

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
22.	MDCG rules of procedure / guidance development	Various stakeholder e.g. MDCG / NBCG med / CAMD Guidance or other interpretation of MDR legal text	The MDCG functions as a de facto rule maker without formal attribution of competence and without transparent procedural rules for stakeholder participation and decision making / voting. Many of the MDCG guidance documents contain new implementing rules rather than guidance for existing rules. Member States require notified bodies to apply MDCG guidance as if it were mandatory requirements. Also, the MDCG guidance documents regularly contain legal mistakes or are inconsistent / incoherent with EU requirements in mandatory law. Finally, MDCG guidance is applied inconsistently between Member States, such as MDCG 2022-5.	The MDCG should <u>contribute</u> to guidance development as foreseen in article 105 (c) MDR and not be finally responsible for the development of guidance. It is problematic that its procedural rules are not transparent and insufficient. Interpretation of the law is Commission prerogative, which means that the Commission should own the drafting process of guidance and provide quality control regarding consistency and coherence of (draft) guidance with EU law, e.g. via its Legal Service. This means that the Commission is owner of the drafting process and uses its legal service for ensuring	• Correct application of Article 105 (c) MDR – no specific change of legislation needed.	Adapt MDCG Rules of Procedure. Correct Point 1 (3) to reflect actual responsibility of DG Health. Include rules regarding the development of Guidance documents and clarify that in accordance with Article 105 (c) MDR the MDCG and its working groups contribute to the development of guidance by the Commission. To this end the MDCG may provide proposals to the Commission for guidance proposed to	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			Furthermore, existing rules of procedure are outdated. Point 1 (3) of the MDCG's Rules of Procedure still provides that "The MDCG shall be chaired by a representative of DG Internal Market, Industry, Entrepreneurship and SMEs."	guidance quality, consistency and coherence. The Commission is responsible for stakeholder feedback as per Better Regulation requirements.	• Amendment of MDCG rules of procedure to reflect the actual responsibility of DG Health and to include an article on guidance development	be adopted by the Commission, which the services of the Commission may evaluate with respect to quality and consistency with other Regulation (EU) 2017/745, Regulation (EU) 2017/746 or EU requirements, amend and subsequently adopt or not. Additionally, reform the procedure in regard to consistent stakeholder consultations and voting.	Short term

5. Further measures to facilitate the MDR / IVDR implementation

a. Digitisation/Digitalization

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
23.	Implant card | Provision digitally	Guidance or other interpretation of MDR legal text Lack of optimisation (considering the state of the art)	Digital provision of the implant card would allow meeting the requirements in article 18 (1) and (2) MDR better. • This ensures that the implant card data in article 18 (1) are always available to the patient "by any means that allow rapid access to that information" and possibly others (e.g. HCPs) regardless of whether the patient is in possession of the physical implant card. • It makes the link between implant card and implanted devices more direct. Health institutions no longer need to match the device and the implant card information physically. • It also manages the risks related to the filling in of the physical implant card by the HCP (see section 7 of MDCG 2019-8 Rev 2). The HCP can be assisted by electronic means or the digital implant card can automatically	Article 18 MDR states that the implant card must be 'provided' but does not exclude that this happens via electronic means. In fact, article 18 (1) states that it can be provided "by any means that allow rapid access to that information". There is experience with provision of e-Labelling information at EU level with respect to clinical trial medicines, which would be a useful template.[7]	Change MDCG 2019-8 Rev 2 (and possibly MDCG 2021-11) to explicitly clarify that the implant card can be provided by digital means as well. MDCG 2019-8 Rev 2 states that "Ways could be explored by relevant stakeholders to develop common rules on how the necessary information to be placed on the System IC is delivered with the replaceable component and how health professionals could ensure that the System IC is appropriately updated, when necessary." This and other ways to harmonise the technical format of the digital implant card[8] could be addressed in a revised version of the MDCG guidance after stakeholder consultation.		Short term

[7] https://circulardigitalhealth.eu

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			be populated from the patient's HER, thus eliminating risks. • Electronic implant cards can accommodate for the situations of revisions of (components of) implantable devices (see MDCG 2019-8 Rev 2 section 8) by updating the electronic implant card. • Electronic implant cards are more durable and issues with information wearing (as can be the case with handwritten implant cards) can be avoided. Electronic implant cards can be provided in a format that can reside in or be linked to the patient's EHR.				
24.	e-Labelling	MDR requirement	e-Labelling can take place by means of a data matrix that gives access to a web page with all elements required under Annex I 23.2 MDR. In addition, the following information from Annex 23.2 MDR should appear on the label:	There is experience with provision of e-Labelling information at EU level with respect to clinical trial medicines, which would be a useful template.[9]	**[option 1]** Article 5 (6) MDR: Commission to adopt **implementing acts** regarding Annex I MDR for practical application.		Short term

[9] https://circulardigitalhealth.eu

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			(a) the name or trade name of the device; (g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate; (h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII;		**[option 2]** Article 9 (1) MDR: Commission to adopt **CS regarding GSPR**s in Annex I chapter III MDR by implementing act		Short term
25.	eIFU	MDR requirement Lack of optimisation (considering the state of the art)	The risks managed in Implementing Regulation (EU) 2021/2226 are no longer current, and therefore redundant. In addition, the use of eIFUs can lead to significant reduction of the use of paper and reduction in CO2 as a result of weight / size reduction.	Implementing Regulation (EU) 2021/2226 has been caught up by reality as the risks that it purports to manage regarding availability of internet for professional and lay users are no longer state of art. These risks have not been amended since Regulation (EU) 207/2012, while availability of internet and robustness of internet connections have developed	Repeal / adapt Implementing Regulation 2021/2226 and address eIFU aspects in Annex I 23.1 and 22 MDR (as regards lay user specific requirements).	The possibility to provide IFU in electronic form applies to all medical devices and accessories. Users should always have the possibility to obtain those instructions for use in paper form upon request.	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				enormously since then. Experiences with other jurisdictions that allow eIFU have confirmed this. The US, for example, allows for eIFU for all medical devices, regardless of professional or lay use. Finally, eIFU would allow for the medical devices to meet obligations under the Accessibility of Products and Services Directive.[10] This directive also has medical devices in scope and imposes, among other requirements, accessibility - requirements that conflict directly with MDR IFU requirements, such as that Information on the use of the product must[11] (i) be made available via more than one sensory channel, while the MDR explicitly limits the availability of the IFU to one sensory channel (writing on paper), (ii) presented to users in ways they can perceive (which is not	[**option 1**] Article 5 (6) MDR: Commission may adopt implementing acts regarding Annex I for practical application		Short term
					[**option 2**] Article 9 (1) MDR: Commission may adopt CS regarding Annex I chapter III by implementing act.		Short term

[10] DIRECTIVE (EU) 2019/882 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 April 2019 on the accessibility requirements for products and services

[11] DIRECTIVE (EU) 2019/882 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 April 2019 on the accessibility requirements for products and services, Annex II section 1 sub 1 (a).

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				possible under the MDR for users that cannot perceive information in a standard paper IFU, e.g. because they are blind) and (iii) be presented in fonts of adequate size and suitable shape, taking into account foreseeable conditions of use, and using sufficient contrast, as well as adjustable spacing between letters, lines and paragraphs (which is not possible under the MDR because a paper IFU cannot accommodate this requirement).	[**option 3**] Amend MDR text for Annex I sections 22 and 23.1		Mid term
26.	e-Signatures	Notified Body practice Lack of optimisation (considering the state of the art)	Not all notified bodies accept digital signatures as a valid document control measure, with is contrary to the e-IDAS regulation[12] (article 25[13]). Notified bodies may not refuse an electronic signature only because it is electronic. This is also linked to the lack of harmonisation of technical	QMS standards require the control of documents (ISO 13485:2016 sections 4.2.4 and 4.2.5). Electronic signature solutions provide a means to authenticate users and protect documents. A so-called advanced electronic signature in the meaning of article 3 (11)	• Simple application of e-IDAS regulation articles 25 and 26[14] Member States to instruct notified bodies not to refuse electronic signatures contrary to article 25 e-IDAS		Short term

[12] REGULATION (EU) No 910/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC

[13] "An electronic signature shall not be denied legal effect and admissibility as evidence in legal proceedings solely on the grounds that it is in an electronic form or that it does not meet the requirements for qualified electronic signatures."

[14] REGULATION (EU) No 910/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			documentation format (see further above).	and 26 e-IDAS Regulation meets these criteria as it: (a) it is uniquely linked to the signatory; (b) it is capable of identifying the signatory; (c) it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under his sole control; and (d) it is linked to the data signed therewith in such a way that any subsequent change in the data is detectable.	• Furthermore, option to include e-signature specification in harmonised TD structure (see further above). • Member States to instruct notified bodies not to refuse electronic signatures contrary to article 25 e-IDAS.		

b. Classification

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
27.	Classification of single use surgical instruments and Up-Classification of reusable surgical instruments in class III	MDR requirement Competent Authority practice MDCG guidance	**1. Classification of single use surgical instruments** According to the rule 6 of the MDR, all surgically invasive devices intended for transient use are classified as class IIa unless they are reusable surgical instruments, in which case they are classified as class I. The guidance on classification (MDCG 2021-24) lists examples for surgically invasive devices according to rule 6. While "Single use scalpels" are class IIa, the "scalpels" are class I if they are reusable. As a consequence, a surgical instrument which is supplied sterile and is intended for single use is classified in a higher risk class (IIa) than the same device which is labelled as reusable (class I) and thus must be cleaned, disinfected and sterilized by the user before the first use and each subsequent use. This differentiation is not comprehensible and even	The solution is to classify all surgical instruments for transient use in the same risk class, being class Ir.	• Option 1: Implementing act on the basis of Art. 51 (4) MDR	• Implementing act clarifying that all surgical instruments for transient use are classified as class 1r	Short term
					• Option 2: Revision of rule 6, 2nd indent by means of legislative change to MDR text or by means of corrigendum (given the contradiction between single use and reusable surgical instruments.	• A corrigendum can be used given the contradiction between single use and reusable surgical instruments. Corrigenda have been used before to amend the MDR (translational regime).	Short term
					• Corresponding revision of MDCG 2021-24 regarding rule 6.	• Revision of rule 6, 2nd indent: "All surgically invasive devices intended for transient use are classified as class IIa unless they … are reusable or single-use surgical instruments, in which case they are classified as class I."	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			contradictory. The reuse of a device requires further processing by the user and bears a higher risk than a device which is already supplied sterile and for single use only. **2. Classification rule 6 of reusable surgical instruments (Annex VIII, 5.2)** According to the rule 6 of the MDR, all surgically invasive devices intended for transient use are classified as class IIa unless they are - intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; - are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III.”	The solution is to classify all surgical instruments for transient use in the same risk class, being class Ir.	• Amend article 52 (7) MDR to bring single use surgical instruments also under Ir conformity assessment procedure. • Option 1: Implementing act on the basis of Art. 51 (4) and (5) MDR • Amend article 52 (7) MDR to bring reusable surgical instruments also under Ir conformity assessment procedure.	• Amend article 52 (7) MDR: “are reusable or single use surgical instruments”. • Implementing act clarifying that all surgical instruments for transient use are classified as class 1r, or that the indents mentioned in Rule 6 do not apply in principle to reusable surgical instruments	Mid term Short term Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
28.	Relationship between timeframe for transient use and classification of surgical devices	MDR Requirement EN ISO 10093	Surgical Devices (including surgical instruments and independently of reusability or invasiveness) are classified according to Rule 6 (transient use, up to 60 min.) or according to Rule 7 (short term use, up to 30 days) depending on the intended duration of continuous use. This incentivises the manufacturer to set the intended use-time to 59 min. especially for reusable surgical instruments, which may be classified as a class I device under indent 2 in Rule 6. While no such indent exists under Rule 7. For real applications, especially in the case of unforeseen complications and prolonged intervention times in the OR, it is not practical to track the duration of use for e.g. scissors or optics. Furthermore, removing surgical devices during an operation due to the legal threshold of application time could pose a risk to patients. This is further exacerbated by the fact that in connection to Annex VII Chapter II 3.6. the calculation of continuous application time may vastly exceed the actual use-time of the devices.	The narrow time-window for transient use may lead to increased risk for patients due to potentially unforeseen legal requirements, to replace a surgical device during a procedure. In accordance with EN ISO 10093 products subject to rule 6 undergo an evaluation including 24 hours of application ensuring biocompatibility, the major risk factor associated with extended use in this context.	Option 1: Implementing act on the basis of Art. 51 (4) MDR	Option 1: Adaptation of rule 7 for additional integration of second indent of rule 6 (to be seen in combination with proposal No. 27). OR Option 2: Revision of the Definition of transient use (Annex VIII, chapter I, 1.1). Adapting the timeframe from 60 min. to 24 h. This would be in line with EN ISO 10993 *"Limited exposure (A) – medical devices whose cumulative sum of single, multiple or repeated duration of contact is up to 24 h."*	Short Term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
29.	Classification of accessories to active implants in class III (Annex VIII, rule 8)	MDR requirement Competent Authority practice MDCG guidance	Classification of accessories to active implantable devices in class III leads to a severe increase in administrative burden for the devices compared to the situation where the normal classification logic is followed. For example, devices that would normally by in class I (e.g. torque wrench for pacemaker) are in class III without any safety or performance advantage.	The increase in administrative burden for the accessories goes against the classification logic laid down in the implementation rule 3.2 of Annex VIII[15] and is an illogical exception to essential classification that is a regulatory artifact from the fact that the AIMDD did not contain a separate concept of accessory, contrary to its later and more evolved successor for medical devices, the MDD. The up-classification and departure from classification logic for this category of devices is not supported by management of risk or increase of safety, since many of these devices, when classified in their own right, would be class I or IIa devices.	[**option 1**] Change MDCG 2021-24 to clarify that accessories to active implants are subject to the implementing rule 3.2 in Annex VIII and therefore classified in their own right.	A corrigendum can be used to exclude accessories from rule 8. Corrigenda have been used before to amend the MDR (translational regime).	Short term
					[**option 2**] Change text of Annex VIII, rule 8, 6th indent to exclude accessories and change MDCG 2021-24 guidance by means of corrigendum		Mid term
					[**option 3**] by means of implementing act based on Article 51 (4) MDR		Short term
30.	Clarification of classification rule 8 for dental products	MDR requirement MDCG Guidance NB practice	In rule 8 is stated that implantable devices and long term surgically invasive devices are classified as class IIb unless they: - Are intended to be placed in the teeth, in which case they are classified in class IIa		Amendment of the Classification Guidance MDCG 2021-24 to ensure correct classification and harmonisation.		Short term

[15] "Accessories for a medical device shall be classified in their own right ◄ separately from the device with which they are used."

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			In practice, however, NBs interpret rule 8 in the way that dental products are classified in higher risk classes according to the following intends of rule 8. This is contradicting the risk-based approach and leads to incorrect classification.				
31.	Classification of software (Annex VIII, rule 11)	MDR requirement Notified Body practice Competent Authority practice MDCG guidance	In practice competent authorities and notified bodies assume that all software in scope of the MDR is class IIa or higher and that class I classification in rule 11 is only available to very specific cases of devices (fertility apps). Yet, by the wording of rule 11 it applies only to devices that are "intended to provide information which is used to take decisions with diagnosis or therapeutic purposes" or are "intended to monitor physiological processes". All other software would be class I according to the text of the classification rule.	Notified bodies and competent authorities feel unable to consider nuanced argumentation that supports that a software device can be in scope of the MDR and yet not intended to be used to take decisions with diagnosis or therapeutic purposes. This is the case for accessories (which do not have a medical intended purpose of their own) in the meaning of article 2 (2) MDR and for medical devices in scope of the definition of medical device in Article 2 (1) MDR but with a different intended purpose than to be used to take decisions with diagnosis or therapeutic purposes, e.g. (artificially intelligent) software that controls an exoskeleton for patients with disability. Such software is not intended for diagnostic or therapeutic	• Clarify element in rule 11 "used to take decisions with diagnosis or therapeutic purposes" in MDCG guidance MDCG 2021-24 under heading "General explanation of the rule" in light of the elements of the definition of medical device such as prevention, alleviation, compensation for, an injury or disability and replacement or modification of the anatomy or of a physiological or pathological process or state; which do not concern provision of information for taking decisions with diagnosis or therapeutic purposes		Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				purposes but rather for alleviation of a disability. This would concern software with intended purposes of prevention, alleviation, compensation for, an injury or disability and replacement or modification of the anatomy or of a physiological or pathological process or state, which will for example comprise (artificially intelligent) software for assisted living and companionship of persons with a degenerative mental disease.	• clarification that all accessories in the meaning of Article 2 (2) MDR are not "intended to provide information which is used to take decisions with diagnosis or therapeutic purpose" or are "intended to monitor physiological processes" in the meaning of rule 11.		
32.	Amendment to classification rule 14	MDR requirement	Many dental filling materials contain such substances and would have to be classified as class III. This would require a disproportionate amount of resources for both manufacturers and notified bodies and is in no way justifiable with regard to relatively low-risk products.	According to Recital (59) of the MDR the objective is to obtain a suitable risk-based classification of devices. This should also be the case for products falling under Rule 14. The classification rule should take into account if the medicinal substance has an impact on the intended purpose of the device. If this is not the case, then it is not justifiable to classify those products under the highest risk class.	**Option 1:** by implementing act via Article 51 (4) MDR **Option 2**: Amendment to Annex VIII Rule 14 MDR "All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point	Clarify that Rule 14 only applies is the medicinal substance has an impact on the intended purpose of the medical device. If this is not the case, the medical device should not be classified under class III according to Rule 14.	Short term Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
					10 of Article 1 of that Directive, and that has an action ancillary to that of the devices and where such substance has an impact on the intended purpose of the device, are classified as class III		
33.	Amendment to classification rule 19	MDR requirement	The European Parliament had already reduced the up-classification to Class III only when the use of nanomaterials is intentional and part of the intended use of the product (amendments 2 and 304), In its justification, the Parliament stated that "many medical devices contain nanomaterials, but do not pose any danger to the patient."	The risk of the use of nanomaterials shall be taken into account in the risk assessment process. However, too many products with no serious concern for health may fall under this rule. Some of these products have been distributed without incidents for years.	**Option 1**: by implementing act based on article 51 (4) MDR **Option 2**: Amendment to Annex VIII Rule 19 MDR as follows: "Rule 19 All devices incorporating or consisting of nanomaterial are classified as: — class IIb if they present a high or medium potential for internal exposure; — class IIa if they present a low potential for internal exposure; and — class I if they present a negligible potential for internal exposure."		Short term Mid term
34.	Classification rules according annex VIII Article 1.10 IVDR .	IVDR requirement	Each of the classification rules shall apply to first line assays, confirmatory assays and supplemental assays.	The risk for the patient should be reflected in the classification of the device.	Update and define in MDCG guideline 2020-16 lower risk classes for additional / suppl. Assays,		Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			IVD for a direct/final detection and direct diagnosis have a higher risk. IVDs where additional tests (e.g. several parameters are needed) are necessary for a final diagnosis have lower risk.		should be classified in their own.		
35.	Classification of class B devices IVDR | Self-assessment	IVDR requirement	IVDR: self-certification of low-risk products (class B) to reduce the burden on the system and eliminate bureaucratic reports with no patient benefit	For the IVDR the policy choice was made to enormously increase the devices under the requirement for notified body conformity assessment where these devices were subject to self-assessment under the IVDD: 736%. This policy decision has not been motivated by safety or performance issues with IVDs under the IVDR and does not serve a purpose of increasing patient safety or test performance. As a result, the conformity assessment system under the IVDR is congested with a large amount of low risk (class B) devices that used to be subject to self-assessment, but for which notified body capacity under the IVDR is scarce and of which the added value of notified body conformity assessment is questionable. This creates an enormous extra cost to the healthcare system that is not justified by any benefits in terms of increased	Amendment of Article 48 (9) IVDR as follows: 9. Manufacturers of class B devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, ~~and including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex for at least one representative device~~ per category of devices. In addition to the procedures referred to in the first subparagraph, for devices for self-testing ~~and near-patient~~ testing, the manufacturer shall follow the procedure for assessment of the technical documentation set out in Section 5.1 of Annex IX.		Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
				performance or safety of tests. The Impact Assessment for the IVDR stated that adoption of the GHTF classification structure for IVDs would necessarily mean conformity assessment for class B devices by a notified body. This does however not follow as a necessary option from GHTF recommendations for IVD conformity assessment, as these also allow for competent authority ex-post supervision on this point as an alternative to notified body assessment. Accordingly, this has been an EU policy choice, which may be revisited. There is all the more reason to revisit this choice and calibrate its consequences, because the expected benefits of the implementation of the GHTF risk classes have not led to the benefits justifying this policy choice that were expected in the Impact Assessment. The Impact Assessment predicted a significant increase in costs for manufacturers (which indeed took place) but justified these based on "enhanced robustness of the classification system, as well as international	Amendment of Annex IX, Chapter II: Delete class B and Chapter 5 delete class B and near patient test. Removing class B devices from the requirement of notified body conformity assessment pursuant to article 48 (9) IVDR would create much needed relief of congestion in the conformity assessment process and unnecessary costly formalities for class B devices. This was also originally foreseen in the IVDR proposal in article 40 (4). The requirement of sampling of technical documentation in article 48 (9) IVDR was added later. Removing the sampling requirement would free up the resources to allow both manufacturers and the few available notified bodies to concentrate on conformity assessment of more complex and/or higher risk devices for which where notified body conformity assessment has added value from a performance and		

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				harmonisation". So far the advantages that underly this policy choice have not materialized and industry does not expect them to materialise without recalibration of the IVDR's certification process.	safety perspective: the class C and D devices.		

c. Gold plating and overlapping legislation

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
36.	Change of language requirements concerning devices intended for healthcare professional	MDR requirement	According to Art. 10 (11) MDR, manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. This Article does not differentiate between lay persons and healthcare professionals. English is a commonly understood language for health care professional. Therefore, the information set out in Section 23 of Annex I should be provided in English if the device is intended for healthcare professionals.		Amendment to Art. 10 (11) MDR: Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. For devices made available to healthcare professionals, the device is accompanied by the information set out in Section 23 of Annex I in English. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.		Mid term
37.	National Databases | Notification of economic operators and devices	National gold-plating	As a result of the delay in Eudamed becoming available on a mandatory basis certain Member States require national notification of devices in diverging local databases. This leads to a significant administrative burden on manufacturers	Eudamed should become applicable as soon as possible for the finished modules. Member States should be made clear that they can no longer require national notification. Eudamed compliance must be made possible to the exclusion of national requirements.	Amend article 123 (3) (e) MDR.A manufacturer that has entered the data in the voluntary modules of Eudamed this excludes national requirements and that this also triggers drag along of the NB and other requirements (SSCP and	Add to article 123 (3) (e) MDR "Member States shall not impose any additional notification or registration obligations for devices for which manufacturers have entered the	Short term in practical implementation by MS

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
					PSUR) under article 123 (3) (ea) – (ec) MDR.	information to be entered in Eudamed in accordance with Article 29 into the relevant Eudamed module(s) available before publication of the notice referred to in Article 34(3)":	mid term by legal changes
38.	National rules and regulations	MDR/IVDR provisions	Review of the opening clauses for the Member States for their necessity and effectiveness	The final sentence of the MDR is "This Regulation shall be binding in its entirety and directly applicable in all Member States." Recital (1) defines the key objectives of the MDR: to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation. However, each Member State has specific national regulations that apply in addition to the MDR. The MDR itself provides for such national opening clauses, allowing national legislators to make independent regulations. However, a relatively large number of opening clauses means that in practice – contrary to a uniform	• All opening clauses of the MDR that allow national supplementary or implementing regulations or delegate them to Member States must be critically evaluated for their necessity and effectiveness. • The possibility of national supplementary regulations must be reduced to an absolute mini-mum and should no longer be permitted in the area of substantive regulations relating to securing the marketability of medical devices on the Union market (including clinical trial legislation). • Where possible, the Medical Device Regulation must constitute an exhaustive regulation for		Short term in practical implementation by MS mid term by legal changes

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
				application of the EU medical device legislation – numerous national peculiarities exist. These national regulations are certainly necessary and useful as far as questions of the jurisdiction of the authorities or penalties pursuant to Article 113 MDR are concerned, which must be adapted to national rules on penalties. However, any additional substantive national regulations that prevent the uniform implementation of the medical device legislation within the Member States must be rejected. Examples include the additional registration of distributors under national law (Article 30(2) MDR), other double registrations in national databases, a sometimes completely different understanding of the term "custom-made devices" or the regulation of other clinical trials, which is largely left to national law (Article 82 MDR) as well as other possibilities for national procedural provisions under the clinical trial legislation. The more national regulatory leeway there is with regard to	medical devices within the EU. • To the extent that national supplementary law is essential (for example, to regulate the responsible authorities in the respective Member States), all national regulations must be made available centrally in order to be binding, at least in an English translation, so that economic operators, users, and other authorities are able to understand these national regulations and, if necessary, implement them. • The contra legem application of special national regulations and administrative practices in the Member States, despite the primacy of EU law, must be monitored and sanctioned much more strictly. To this end, effective mechanisms must be created, for example, at the level of the Medical Devices Coordination Group (MDCG).		

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
				formal and material requirements for medical devices, the greater the resource and cost expenditure for manufacturers and other economic operators to research and implement special national regulations within the EU, provided that these regulations can be determined with any legal certainty in the very different national systems and in view of language barriers. The more national regulations there are, the greater the risk – which has been confirmed time and again in practice in recent years – that national legislators and authorities will issue, interpret, and apply regulations in clear contradiction to the overriding legislation of the MDR. This poses an immediate threat to the smooth functioning of the internal market (Recital (2), Sentence 1 MDR).			
39.	Overlapping <u>substantive</u> requirements with other (horizontal) EU regulation	MDR requirement	MDR lacks a clear hierarchy provision for horizontal legislation. Multiple regulations can apply that impose different, overlapping or contradictory essential requirements. The EU's Blue Guide states that "Two or	A hierarchy clause regarding essential requirements should be included in article 1 MDR, and it should be broad enough to cover all overlaps between MDR and horizontal regulation	Adopt a hierarchy provision based on the model for overlap other legislations e.g. with the Machinery Regulation.	As an example: Amend article 1 (12) MDR: "Devices that are also ~~machinery~~ a regulated product in scope of other Union product	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
			more Union harmonisation acts can cover the same product, hazard or impact. In such a case, the issue of overlap might be resolved by giving preference to the more specific Union harmonisation act."[16] While there are some provisions for this purpose in the MDR with respect to electric magnetic compatibility (EMC) and Machinery, other product regulations are not addressed, nor does the MDR contain a mechanism for applying the Blue Guide logic that the more specific regulation applies (or to determine which one is the more specific regulation).	that also applies to medical devices.		regulation ~~within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (~~[2]~~)~~ shall, where a hazard relevant under that Regulation or Directive exists, also meet the essential ~~health and safety~~ requirements set out in the relevant Annex I to that Regulation or Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in this Regulation.	
40.	Overlapping specific requirements with other EU product regulation	MDR/IVDR requirement	MDR/IVDR lacks a clear hierarchy provision for horizontal legislation. The EU's Blue Guide states that "Two or more Union harmonisation acts can cover the same product, hazard or impact.	The Commission should be able to determine by delegated act whether an overlapping regulation is more specific than the MDR and for what specific	Adopt a mechanism for the Commission to establish hierarchy in specific cases.	The following Article 1 (17) (a) is inserted: "The Commission is empowered to adopt delegated acts in	Mid term

[16] Blue Guide 2022, section 2.7

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			In such a case, the issue of overlap might be resolved by giving preference to the more specific Union harmonisation act."[17] While there are some provisions for this purpose in the MDR/IVDR with respect to electric magnetic compatibility (EMC) and Machinery, other product regulations are not addressed, nor does the MDR contain a mechanism for applying the Blue Guide logic that the more specific regulation applies (or to determine which one is the more specific regulation).	requirements it should apply to a device in scope		accordance with Article 115 in order to amend Article 1 to determine hierarchy of specific requirements pursuant this Regulation in relation overlapping or conflicting requirements in other Union legislation."	
41.	Overlapping requirements between MDR/IVDR and AI Act	MDR/IVDR requirement	MDR/IVDR lacks a clear hierarchy provision for horizontal legislation, also as regards procedural requirements that double requirements under the MDR. For example, Post Market Monitoring (PMM) under AI Act and PMS under the MDR overlap.	As an example: The AI Act and the MDR/IVDR have overlapping PMS systems. The AI Act gives providers of an AI system the "choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2 and 3 using the template referred in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection". Paragraph 3 provides that the Commission shall adopt an implementing act	AI Office, AI Board, Advisory Forum, Commission, MDCG, and working groups to consult and work together in all aspects related to issues due to overlapping requirements in MDR and AIA. In regard to the example provided: The development of the PMM template in article 72 (3) AI Act must ensure that it is fully consistent with already existing MDR	Set up transparent procedures between AI Office, Commission, AI Board and MDCG (including responsible working groups) that ensure collaboration, coordination and appropriate decision making to achieve coherence.	Short term

[17] Blue Guide 2022, section 2.7

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
				laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan by 2 February 2026. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2). Given that PMS objectives and logic are well defined in the MDR but not yet in the AI Act, inconsistencies are likely the result. This template will likely not be consistent with the PMS standards under the MDR and cause problems in the implementation because the AI Act uses defined concepts relating to PMM that are different from defined MDR concepts for PMS, such as the definition of serious incident.	requirements/templates and does not impose any other burden than monitoring the compliance with the requirements in Chapter III section 2 AI Act (articles 8-15)		
42.	Divergent definitions of substantial change under MDR/IVDR (not defined) and definition of 'substantial	MDR requirement	A medical device may also be an AI system and a substantial change to the device may or may not be a substantial modification under the AI Act. Substantial modification is defined in the AI Act. Difference in definitions would lead to the situation that a change to an AI System that is also a medical device or IVD may				Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
	modification' in AI Act (article 3 (23)".[18]		need to be notified under both MDR/IVDR and AI Act or under either and under separate criteria, which makes necessitates two QMS-es for one product.				

[18] "'substantial modification' means a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 2 is affected or results in a modification to the intended purpose for which the AI system has been assessed"

d. Other

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
43.	Substantial changes **to QMS** / Definition / process (Annex VII 4.9, Annex IX, 2.4)	Divergent notified body practice	The MDR/IVDR requires planned **substantial** changes to the quality management system, or the device-range covered to be notified to the notified body so the notified body can evaluate if the proposed substantial change requires additional audits. The issue is that the concept of substantial change is not defined in the MDR, leading notified bodies to require manufacturers to notify them of *any change* (each using their own different change notification process and forms), after which the notified body takes time and fees to evaluate if the change is substantial. causing administrative delays and extra costs for manufacturers. Currently, there are significant delays in assessing substantial changes to the QMS making it nearly impossible for manufacturers to plan. Additionally, timelines for assessment of substantial changes differ greatly between NB.	Notified bodies are unable to come to a clearly delimitated and harmonised scope of the concept of substantial change, in other words what constitutes a substantial change to the quality management system, or the device-range covered and to provide a harmonized notification template. Since this has already been defined once in NBOG BPG 2014-3, the MDCG can update this guidance to current state of art. As regards batch notification there is nothing in the MDR that prevents batch notification. The MDCG has provided in MDCG- 2019-6 Rev. 4 Question IV.9 that "With regard to [substantial changes], the CAB needs to make clear in its communication to the manufacturer (e.g. in the terms and conditions) what it considers as "substantial changes" to the quality management system or the device-range covered. In order to fully comply with all the relevant requirements, the CAB must have documented procedures defining how	Implementing act pursuant to article 36 (3) MDR to address the challenges in regard to change notifications by providing mandatory detail in Annex VII section 4.9, last sentence about what the notified body specifically have in terms of procedures and what these procedures look like.	The implementing act pursuant to article 36 (3) MDR and in regard to change notification should amend Annex VII section 4.9 in the following respects: : • Provide for a definition and common understanding of what constitutes a "substantial change" that needs to be notified by the manufacturer (COM can build on already existing NBOG BPG 2014-3 and should also take into account developments in other applicable legislation such as the AIA that addresses "substantial modifications") • Clarify that manufacturers evaluate changes in accordance with	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			Another problem is that there is no process for 'batch' notification.	different changes need to be notified and assessed prior to their implementation and how the assessment will be documented." The root cause of the problem is that although the MDCG has made it clear that notified bodies can be practical on this point they are not in practice. Since notified bodies are not able to harmonise this, an implementing act to address these issues is necessary. It should be possible to use a Predetermined Change Control Process (PCCP) by analogy to the AI Act (Pre-determined change control plan (article 43 (5) AI Act) as well as obtain batch approval for – foreseen changes.		their audited QMS procedures • Clarify that non-substantial changes neither need notification nor approval • Determine a maximum duration for the NB to assess the notified substantial changes as well as further measures. • Incorporate a provision that allows manufacturers procedure to determine if a notified change is substantial, e.g. 30 days plus the right of the manufacturer to implement the change as non-substantial if the notified body does not decide within the given time frame (e.g. 30 days); • Clarify the procedure to evaluate a substantial change;	

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
						• Explicitly include that the NB must have a process to accept both single and batch notifications for substantial changes. • Include a provision for planned changes in surveillance audits and permit a predetermined change control process (PCCP).	
44.	Substantial changes **to devices** / Definition / process (Annex VII 4.9, Annex IX, 4.10)	Divergent notified body practice	Annex IX 4.10 MDR requires that changes to an approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate ***"where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device."*** Only such changes may be considered "substantial". The issue is that substantial changes in this regard are not defined in the MDR, leading notified bodies to require manufacturers to notify them of *any change* (each using their own different change notification process and forms),	Notified bodies do not have a clear understanding of what changes to the device are substantial and require approval. There is no harmonized template and approach which leads to diverging practices. Since NB must have documented procedures defining how different changes need to be notified and assessed prior to their implementation, how the assessment is documented, these decisions have direct impact on manufacturers, and previous calls of the MDCG for "practical implementation" are	**Implementing act pursuant to article 36 (3) MDR to address the challenges in regard to change notifications.**	The implementing act pursuant to article 36 (3) MDR and regarding change notification should contain the following aspects: • Provide for a definition and common understanding of what constitutes a "substantial change" in regard to devices that needs to be notified by the manufacturer (also take into account developments in other applicable legislation such as	Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			It is essential to understand, that Annex IX 4.10 requires notification **and approval by a NB** of substantial changes (changes that affect safety and performance of the device or the conditions prescribed for use of the device). if the manufacturer plans to introduce such changes. Currently, there are no timelines for NB to assess changes, which, in practice, leads to significant delays of such assessments. This uncertainty and these delays are inacceptable as they make it nearly impossible for manufacturers to plan. Moreover, delays have a direct and very negative impact on manufacturers that have no market access for the impacted product without approval of the NB. Additionally, timelines differ greatly between the NB for the assessment, if the changes require a new conformity assessment or if the changes can be addressed by means of a supplement to the technical documentation assessment certificate.	not resonating, an implementing act to address these issues is necessary.		the AIA that addresses "substantial modifications") • Clarify that manufacturers evaluate changes in accordance with their audited QMS procedures • Clarify that non-substantial changes neither need notification nor approval • Determine a maximum duration for the NB to assess the notified substantial changes and further measures. • Incorporate a provision that allows manufacturers to implement the change if the notified body does not decide within the given time frame (e.g. 30 days); • Clarify the procedure to	

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			Another problem is that there is no process for 'batch' notification.			evaluate a substantial change; • Explicitly include that the NB must have a process to accept both single and batch notifications for substantial changes. • Include a provision for planned changes in surveillance audits and permit a predetermined change control process (PCCP).	
45.	PSUR and PMS report frequency	MDR/IVDR requirement	Pursuant to article 86 (1) MDR/article 81 (1) IVDR Manufacturers of class IIb and class III/ class C and D devices shall update the PSUR at least annually and class IIa/C devices at least every two years. This applies to both MDR devices and legacy devices and regardless of any developments that would have importance in the manufacturers PMS system.	This requirement should be changed to updates only when there is a relevant change to report (see also under point SSCP frequency (yearly update) Explanation in relation to PMS and PMCF regarding KRIs).	<u>Periodicity</u> • Amendment to Article 86/81 (1) 2nd and 3rd paragraphs to report only in case of significant changes in the conclusions of the benefit-risk determination or in the main findings of the PMCF/PMPF compared to the date of the initial CE certificate for the device concerned or compared to the last PSUR update.	• Amend article 86/81 (1) 2nd paragraph by deleting "at least annually" and replace this by "in case significant changes in the conclusions of the benefit-risk determination or in the main findings of the PMCF compared to the date of the initial CE certificate for the device concerned or compared to the last PSUR update"	Mid term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					Key Risk Indicators Adopt CS based on article 9 (1) to amend PMCF in Annex XIV to define KRIs for PMCF that would trigger need for PSUR update.	Amend article 86/81 (1) 3rd paragraph by deleting "necessary and at least every two years" and replacing this by "significant changes in the conclusions of the benefit-risk determination or in the main findings of the PMCF compared to the date of the initial CE certificate for the device concerned or compared to the last PSUR update"	short term
46.	Addition of absorbable implants in the list of exemptions from the obligation to have an implant card	MDR requirement MDCG-Guidance 2021-11	The implementation of an implant card is very burdensome. Beside the specifications and material costs, additional production and packaging processes must be installed which impact sterilization and transportation validations. There are many implantable devices which are made of an absorbable material. The absorption time depends on the material and lasts only for a few weeks or months. After the absorption is completed, the implant has gone, and the implant card must be discarded. In fact, the implant		Adoption of a delegated act to amend the list of Art. 18 (3) MDR by adding "absorbable implantable devices". Resulting in Amendment to Art. 18 (3) MDR: "3. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, connectors and		Short term

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	*Description*	Time-frame
			card is useful and beneficial for permanent implants. However, for absorbable products, the suitability and benefits should be reconsidered.		absorbable implantable devices. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom." Amendment of MDCG 2021-11 by removing Nr. 74 Absorbable haemostats.		 Short term
47.	UDI direct marking	MDR requirement	The UDI direct marking requirement for devices used multiple times on a single individual (single patient, multiple use) is excessive[19].	Clarifications in the MDR are necessary to avoid the UDI direct marking requirement for devices used multiple times on a single individual (single patient, multiple use)	• Annex VI, Part C, Section 4.10, Sentence 1 MDR should be deleted without replacement. • At the same time, a MDCG Guidance should be published to clarify that Section 4.10, Sentence 2 (old version) is only applicable to specific medical devices that are intended to be used on multiple patients and intended to be reprocessed between patient uses, as set out in Article 2(39) MDR. Additionally, the definition according to Article 2(39) MDR must be specified as	Amendment of the MDR	Mid term

[19] For the full version see here pp. 4 ff.: https://www.eurocom-info.de/wp-content/uploads/2024/09/2024-09-19_Position-eurocom_Evaluation-MDR.pdf

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					follows to assign reprocessing to a procedure to which a used product is subjected under the responsibility of a professional reprocessor, so that it can be safely reused by a user who is not a layperson. This should include procedures for cleaning, disinfection, sterilization, and similar processes, as well as tests and restoration of the technical and functional safety of the used product.		
48.	Definition and differentiation of custom-made / patient-matched	Diverging interpretations by notified bodies Diverging interpretations by Member States / Competent authorities	The terms “custom made devices” and “mass-produced devices” and/or patient-matched are unclear and interpreted differently. There is no harmonised approach according MDCG 2021-3[20] and IMDRF/PMD WG/N49 FINAL:2018[21]	The considerable legal uncertainties arising from the distinction between custom-made devices and patient-matched devices that require CE marking, as well as surrounding the precise regulatory requirements for manufacturers of custom-made devices run counter to the aim of the MDR to ensure the smooth functioning of the internal market[22].	Clear definitions of the terms “custom-made” and “mass-produced devices” in the MDR: Manufacturers must be able to make the essential distinction between a custom-made device and a patient-matched device as clearly as possible. To this end, the definition of custom-made devices must be clarified.		Short term

[20] https://health.ec.europa.eu/document/download/385d7e20-d8b5-49d0-abd7-8daf269bf1b8_en?filename=mdcg_2021-3_en.pdf

[21] https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181018-pmd-definitions-n49.pdf

[22] For the full version see here pp. 8 ff.: https://www.eurocom-info.de/wp-content/uploads/2024/09/2024-09-19_Position-eurocom_Evaluation-MDR.pdf

	Issue and current requirement	Qualification of bureaucratic issue	Explanation	Rationale	Resolution *Proposed instrument / legal basis for resolution*	 *Description*	Time-frame
					The term mass-produced devices, which has not yet been defined, must be additionally defined in the interest of better differentiation, particularly between custom-made devices and patient-matched medical devices. Consistent definitions should be ensured within the language versions of the MDR. The definition of 'custom-made device' should include, according to a written prescription, the specific design characteristics of the product that is adapted to meet the specific requirements of a particular patient and intended for the sole use by that single patient based on their individual condition and needs. This is to be distinguished from mass-produced devices that are adapted or assembled within a pre-validated range specified by the manufacturer to fit the specific anatomical features of an individual patient. The		

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					definition of 'mass-produced product' should focus on manufacturing and reproducibility in an industrial process. The number of products manufactured should be irrelevant. Requirements for manufacturers of custom-made devices The general obligations of manufacturers under Article 10 MDR in conjunction with the procedure set out in Annex XIII MDR have proven to be inappropriate and overly complex for manufacturers of custom-made devices. As custom-made devices are typically manufactured by small artisanal companies, one of the key objectives of the MDR, namely to ensure the smooth functioning of the internal market taking into account small and medium-sized enterprises, is jeopardised. At the same time, the long-term security of supply of high-quality, individually manufactured medical devices to patients		

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					is at risk if manufacturers of custom-made devices find themselves forced to cease their activities due to non-transparent and inappropriate regulatory requirements. A solution would be to separate regulation for manufacturers of custom-made devices and to completely exclude them from the general obligations of manufacturers under Article 10 MDR and other manufacturer obligations scattered throughout the MDR. The separate regulation for devices manufactured and used only within health institutions laid down in Article 5(5) MDR, according to which such health institutions are generally exempt from the requirements of the MDR when manufacturing devices within the health institution, provided that all of the conditions under Article 5(5) MDR are met (in particular the general requirements according to		

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					Annex I), could be used as a model for such a special regulation. This would require a supplementary provision by adding a paragraph to Article 5 MDR or in systematic connection with Article 10 MDR, according to which the requirements of the MDR do not apply to manufacturers of custom-made products, except the requirements set out in Annex XIII MDR, which also refer to Annex I MDR. This would also solve the often excessive requirement of a person responsible for regulatory compliance under Article 15 MDR, which could then not be invoked for manufacturers of custom-made products up to a certain company size. Moreover, within the framework of such a special regulation for manufacturers of custom-made products, the significant problem in practice that the requirements for clinical evaluation are often hard to implement in a sensible way		

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					could be remedied in a targeted and legally compliant manner through special regulations in Annex XIII MDR.		
49.	Definition Narrow interpretation of the term "surgically invasive" in Art. 58(1a) IVDR, i.e. no inclusion of normal blood samples (harmless quantity for non-vulnerable donors)	In EU there are millions of blood draws every day without tracking patients. These blood draws are even done by medical assistants and not HCP. Under IVDD/MPG (§ 7) this was standard.	Legal uncertainty and, in case of doubt, more approval procedures necessary		Term "surgical invasive" has to be adopted for IVDR or a specific explanation has to be added to ensure that venous blood sampling in adults does not fall under the term 'surgical invasive'. AND This interpretation could, for example, be clarified in the announced MDCG document Q&A on performance studies.		Short term
50.	Double vigilance reporting	Vigilance reports must be made both to the competent authorities and to the notified body while the intention of the MDR is that notified bodies should have automatic access to vigilance data	The intent of the MDR is that notified bodies have automatic access to vigilance information (see Annex VII, section 4.10 last indent), yet notified bodies require separate notification and charge a fee of several hundreds of Euros for just receiving the vigilance notifications. Even if the Eudamed vigilance and PMS module is not available manufacturer should not be subjected to double administrative and costly	Competent authorities can provide the relevant information to notified bodies directly from their databases.	Competent authorities to automatically forward the vigilance reports and follow-up received to the notified body concerned. This can be implemented technically based on the relevant XML fields in the MIR form (notified body, notified body certificate number, device description section in general (2.3 of MIR form).	Amend MDCG 2021-1 Rev.1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional with a line at article 87 that member states report vigilance information that notified bodies would otherwise	Short term

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		(see Annex VII, section 4.10 last indent).	requirements. Charging fees for this is contrary to the fee structure elements set out in MDCG 2023-2.			source from Eudamed based on article 92 to the notified bodies concerned directly.	